



Zee AF

PATENT
Customer No. 22,852
Attorney Docket No. 07883.0106

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

David H. MOWRY

)
)
Group Art Unit: 3743

Application No.: 09/769,746

)
Examiner: K. Odland

Filed: January 25, 2001

)
)
)
Confirmation No.: 5109

For: INTRAVASCULAR
VENTRICULOCORONARY
BYPASS VIA A SEPTAL
PASSAGEWAY

Mail Stop Appeal Brief--Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

TRANSMITTAL OF APPEAL BRIEF (37 C.F.R. 41.37)

Transmitted herewith is the APPEAL BRIEF in this application with respect to the
Notice of Appeal filed on December 9, 2004.

This application is on behalf of

Small Entity Large Entity

Pursuant to 37 C.F.R. 41.20(b)(2), the fee for filing the Appeal Brief is:

- \$250.00 (Small Entity)
 \$500.00 (Large Entity)

TOTAL FEE DUE:

Appeal Brief Fee \$250.00

Extension Fee (if any) \$60.00 (one month, small entity)

Total Fee Due \$310.00

Enclosed is a check for \$310.00 to cover the above fees.

PETITION FOR EXTENSION. If any extension of time is necessary for the filing of this Appeal Brief, and such extension has not otherwise been requested, such an extension is hereby requested, and the Commissioner is authorized to charge necessary fees for such an extension to our Deposit Account No. 06-0916.

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: March 8, 2005

By: Susanne T. Jones
Susanne T. Jones
Reg. No. 44,472

865206_1.DOC



PATENT
Customer No. 22,852
Attorney Docket No. 07883.0106

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
David H. MOWRY) Group Art Unit: 3743
Application No.: 09/769,746) Examiner: K. Odland
Filed: January 25, 2001)
For: INTRAVASCULAR)
VENTRICULOCORONARY) Confirmation No. 5109
BYPASS VIA A SEPTAL)
PASSAGEWAY)

Mail Stop Appeal Briefs
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPEAL BRIEF UNDER BOARD RULE § 41.37

In support of the Notice of Appeal filed December 9, 2004, and further to Board Rule 41.37, Appellant presents this brief and encloses herewith a check for the fee of \$250.00 required under 37 C.F.R. § 1.17(c). A request for a one-month extension of time and appropriate fee payment is filed herewith to extend the due date for filing this Appeal Brief to March 9, 2005.

This Appeal responds to the August 10, 2004 final rejection of claims 1-3, 7, 8, and 22-25.

If any additional fees are required or if the enclosed payment is insufficient, Appellant requests that the required fees be charged to Deposit Account No. 06-0916.

03/09/2005 YPOLITE1 00000103 09769746

01 FC:2402

250.00 OP

Real Party In Interest

Percardia, Inc. is the real party in interest.

Related Appeals and Interferences

There are currently no other appeals or interferences, of which Appellant, Appellant's undersigned representative, or Assignee are aware, that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status Of Claims

Claims 1-10, 14-20, and 22-29 are pending. Claims 11-13 and 21 are canceled.

Claims 1-3, 7, 8, and 22-25 are rejected. Claims 4-6, 9, 10, 14-20, and 26-29 are withdrawn from consideration. The final rejection of claims 1-3, 7, 8, and 22-25 is appealed. The rejoinder of claims 4-6, 9, 10, 14-20, and 26-29, due to their dependence on claims 1 and 24, is requested.

Status Of Amendments

No amendment has been filed subsequent to the final rejection.

Summary Of Claimed Subject Matter

An embodiment of the invention, as set forth in independent claim 1, for example, includes a method for supplementing a flow of blood to a portion of the cardiovascular system of a patient. The method includes inserting a catheter device 102 into the vasculature 111 of the patient 100 and advancing the catheter device 102 to a first location within a first coronary vessel 112 within the cardiovascular system 111. (Figs. 1, 4A; page 15, line 28 through page 16, line 5). The method further includes forming a blood flow path 165 from a heart chamber 150 directly to the first coronary vessel 112 via a preexisting natural septal opening 162 extending into the heart wall 152 between the heart chamber 150 and the first coronary vessel 112. (Fig. 4D; page 16, line 21 through page 17, line 9).

The method may further include, as recited in claim 2 for example, forming a blood flow path 165 from the heart chamber 150 directly to the first coronary vessel 112 by placing a conduit 166 in the heart wall 152 between the heart chamber 150 and the first coronary vessel 112. In addition, the method may include, as recited in claim 3 for example, placing a conduit 166 in the preexisting natural septal opening 162. (Fig. 4E; p. 17, lines 10-11).

Another embodiment of the invention, as set forth in independent claim 24, for example, includes a method for supplementing a flow of blood to a portion of the cardiovascular system of a patient. The method includes inserting a catheter device 102 into the vasculature of the patient 100 and advancing the catheter device 102 to a first location 130" within a coronary vessel 112 within the cardiovascular system 111,

the first location 130" being proximate to an obstruction 122 within the coronary vessel 112, (Figs. 1, 4A; page 15, line 28 through page 16, line 6). The method may further include advancing the catheter device 102 through the obstruction 122 to a second position 132" distal to the obstruction 122. (Figs. 4B-4C; page 16, lines 6-13). The method further includes guiding the catheter device 102 through an interstitial passageway 165 extending into a heart wall 152 between a heart chamber 150 and the coronary vessel 112 and placing a conduit 166 in the interstitial passageway 165 extending into the heart wall 152 between the heart chamber 150 and the coronary vessel 112. (Fig. 4D; page 16, lines 21-28; Fig. 4E; page 17, lines 10-16). The interstitial passageway 165 includes a preexisting natural septal opening 162 extending into the heart wall 152 between the heart chamber 150 and the coronary vessel 112. (Figs. 4A-4E; page 16, line 23 through page 17, line 9).

The use of a preexisting natural septal opening in the heart wall as part of a blood flow path (claim 1) or an interstitial passageway (claim 24), and placing a conduit in the heart wall to form the blood flow path (claim 2) and/or in the preexisting natural septal opening (claims 3 and 24) differ from prior art methods that form passages in heart walls and/or place conduits in those passages without utilizing any preexisting natural septal openings.

Grounds of Rejection To Be Reviewed

Claims 1-3, 7, 8, and 22-25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,409,019 to Wilk ("Wilk").

Argument

At pages 2-7 of the Final Office Action, claims 1-3, 7, 8, and 22-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,409,019 to Wilk. Applicant respectfully traverses this rejection because the Office Action does not establish a *prima facie* case of obviousness.

A. WILK NEITHER DISCLOSES NOR SUGGESTS A PREEXISTING NATURAL SEPTAL OPENING

Wilk discloses a coronary artery bypass method in which a stent 12 is disposed in a wall HW of a patient's heart PH. (Figs. 2A-2B). With reference to Figs. 3A-3E, Wilk discloses an embodiment in which a catheter 20 is inserted into the coronary artery CA and past a blockage BL such that the catheter's distal tip 22 is disposed in a desired location opposite the heart wall HW. (Col. 4, lines 10-16). The distal tip 22 is brought into contact with the wall HW and a rotary head 24 of a surgical drill is ejected. Head 24 is rotated while the catheter 20 is pushed in a distal direction, thereby forming a passage in the heart wall HW. (Col. 4, lines 20-25).

The distal end portion 26 of the catheter 20 is placed in the passage and the surgical drill is withdrawn. Stent 12 is then inserted down the catheter 20 and the catheter 20 is withdrawn leaving the stent 12 behind in the heart wall HW. (Col. 4, lines 25-46).

Figs. 5A-5C depict an embodiment for disposing the stent 12 in the heart wall HW wherein a hollow needle 48 is ejected from the end of the catheter 44 into the heart wall HW. A Seldinger wire 50 is then moved through the catheter 44 and needle 48. (Col. 5, lines 11-20). The needle 48 is then withdrawn and an auxiliary catheter 52 is

inserted through catheter 44 and over the wire 50. (Col. 5, lines 19-23). Catheter 52 is used to measure the thickness of the heart wall HW and is then withdrawn, and a balloon 54 surrounded by a stent 12 is inserted through catheter 44 and over the wire 50. The balloon 54 and stent 12 are positioned inside the heart wall and the balloon 54 is inflated to expand the stent 12 and place the stent 12 in the heart wall. After desired placement of the stent 12 in the heart wall, the balloon 54, wire 50, and catheter 44 are withdrawn. (Col. 5, lines 28-39).

Wilk discloses another embodiment for disposing the stent 12 in the heart wall HW in Figs. 6A-6C. In that embodiment, a catheter 56 is maneuvered to position the distal end 58 in the coronary artery CA and into contact with the heart wall HW. A needle or wire 60 is ejected from the catheter distal end 58 and into the heart wall HW. Thereafter, a series of dilating catheters 62 are inserted through the catheter 56, over the needle 60, and into the heart wall HW. Upon ejection of the largest diameter catheter into the heart wall, the catheter is withdrawn and a balloon 64 carrying a stent 12 is inserted through the catheter 56 and over the needle or wire 50. Once positioned in the heart wall HW, the balloon 64 is inflated and the stent 12 expanded and disposed in the heart wall HW. Thereafter, the balloon 64, wire 50, and catheter 56 are withdrawn. (Col. 5, line 40 - col. 6, line 2).

In the various embodiments Wilk discloses for performing a coronary artery bypass procedure, Wilk does not disclose or suggest either "forming a blood flow path . . . via a preexisting natural septal opening," as recited in claim 1; "wherein forming a blood flow path . . . includes placing a conduit in a heart wall," as recited in claim 2; or "placing a conduit in the preexisting natural septal opening," as recited in claim 3. Nor does Wilk

disclose or suggest “placing a conduit in the interstitial passageway . . . wherein the interstitial passageway includes a preexisting natural septal opening,” as recited in claim 24. Indeed, nowhere throughout the disclosure of Wilk is there any mention whatsoever of a preexisting natural septal opening.

Significantly, the Examiner acknowledges at page 3 of the final Office Action that “Wilk does not explicitly recite a preexisting natural [septal] opening.” See also, final Office Action at p. 4 and 6; and Advisory Action at p. 2. To allegedly cure Wilk’s lack of teaching of a preexisting natural septal opening, the Examiner asserts, however, that “it would have been obvious to one with ordinary skill in the art and within the scope of the invention to use a preexisting opening for the purpose of less drilling. The path of least resistance would be to use an area where there would be less channel formation required and this would be obvious to one of ordinary skill in the art at the time the invention was made.” Office Action at p. 4. For the reasons explained below, however, the Examiner has failed to establish a *prima facie* case of obviousness in view of Wilk.

B. THE FINAL OFFICE ACTION FAILS TO ESTABLISH A *PRIMA FACIE* CASE OF OBVIOUSNESS TO MODIFY WILK

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103, three basic criteria must be satisfied. First, “there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify a reference or to combine reference teachings.” M.P.E.P. § 2142, Original 8th ed., Rev. 2, May 2004, p. 2100-128. Second, “there must be a reasonable expectation of success.” Id. Third, “the prior art reference (or references when combined) must teach or suggest all the claim limitations.” Id. Moreover, “[t]he teaching or suggestion to make the claimed combination and the

reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." (citing In re Vaeck, 947 U.S.P.Q.2d (BNA) 1438 (Fed. Cir. 1991)). Id. In other words, hindsight may not be relied on in establishing a *prima facie* case of obviousness.

The Section 103 rejection based on Wilk fails to satisfy at least the first and third requirements necessary to establish a *prima facie* case of obviousness.

1. The final Office Action fails to provide any suggestion or motivation to modify Wilk

The Examiner's assertion that it would have been obvious to skilled artisans at the time of the invention to modify Wilk by "[using] a preexisting opening for the purpose of less drilling" is completely conclusory and unsupported by any evidence, such as, for example, a teaching found in a secondary reference or elsewhere. Quite simply, the Examiner has not provided any evidence whatsoever to support either the alleged teaching of the acknowledged missing disclosure from Wilk or the alleged motivation to modify Wilk in the hypothetical manner suggested in the final Office Action.

At page 2 of the Advisory Action, the Examiner states

For a surgeon, during surgery, it would be obvious, if not inherent to use a preexisting opening if one exists. A surgeon would not drill a hole next to a preexisting hole, if one existed. . . .In the instant application, there is knowledge generally available to one of ordinary skill in the art to use a preexisting opening if one exists to minimize drilling. A surgeon would have the general knowledge to use a preexisting opening rather than drill another opening right next to it.

The Examiner provides no evidence whatsoever to support the asserted position regarding the "knowledge generally available to one of ordinary skill in the art" or "the general knowledge" of a surgeon. Rather, the Examiner simply offers conclusions as to

the knowledge of skilled artisans and surgeons. Such conclusions, however, fail to satisfy the requirement that a *prima facie* case of obviousness rest on objective evidence and making specific factual findings. See M.P.E.P. § 2143.01 citing In re Lee, 277 F.3d 1338, 1342041 (Fed. Cir. 2002).

Moreover, it is improper to rely on some alleged level of skill in the art as the motivation for making a hypothetical combination. See M. P.E.P. § 2143.01. The M.P.E.P. clearly states that “[i]t is never appropriate to rely solely on common knowledge in the art without evidentiary support in the record as the principal evidence upon which a rejection is based.” M.P.E.P. § 2144.03(E). Yet, such improper reliance on the alleged knowledge of skilled artisans and surgeons is precisely how the Examiner attempts to support a motivation to modify Wilk in the manner set forth in the final Office Action.

Further, the Examiner’s alleged motivation to modify Wilk and use a preexisting opening for the purpose of less drilling completely ignores that at the time of Applicant’s invention skilled artisans may have had reasons not to use such a preexisting septal opening. The Examiner completely ignores that at the time of the invention other skilled artisan “knowledge,” such as, for example, extra time under anesthesia or additional surgical procedures needed for locating preexisting septal openings, could have provided reasons against the proposed modification of Wilk. The Examiner quite simply has provided no evidence on which to base what “knowledge” existed, either by surgeons or skilled artisans, at the time of Appellant’s invention regarding the use of preexisting natural septal openings.

Thus, for the reason explained above, the final rejections based on Wilk are devoid of any evidence setting forth a teaching of the alleged missing disclosure of Wilk, the alleged knowledge of skilled artisans and surgeons, and the alleged motivation to modify Wilk in the manner suggested. For at least these reasons, a *prima facie* case of obviousness has not been established.

2. The Examiner Improperly Relies on Hindsight and Applicant's Own Disclosure as the Motivation to Modify Wilk

Instead of finding a suggestion or motivation to combine, the first requirement of a *prima facie* case of obviousness, the Examiner appears to be relying on the teachings of the present application as motivation to modify Wilk and, with hindsight, uses Appellant's own disclosure in support of the obviousness rejection as clearly prohibited by In re Vaeck.

In particular, at pages 3 and 4 of the final Office Action, in support of the rejection based on Wilk, the Examiner states

Applicant is directed to the current application specification where pages 16-17 recite, 'In situation where an existing opening is used, such as the septal branches 160, 162, the pathway to the heart chamber must be extended to establish communication with the heart chamber 150. For example, as shown in FIG. 4D, a pathway extension 163 can be formed to complete the path to the heart chamber 150. To accomplish this, the catheter device 102 can be equipped with (or used in conjunction with a catheter equipped with) an ablation device, for example, an ablation tip (not shown) capable of ablating or otherwise creating the channel pathway extension 163 between either of the septal branches 160, 162 into the heart chamber 150.' Given this recitation, some portion of the channel must be created. Therefore, although Wilk does not explicitly recite to use a preexisting natural opening, it would be obvious to one with ordinary skill in the art and within the scope of the invention to use a preexisting opening of the purpose of less drilling.

See also, Office Action dated August 10, 2004 at p. 2.

Thus, the Examiner relies on Appellant's own disclosure that teaches to extend a septal branch in the heart wall to form a path to the heart chamber, as set forth in Appellant's specification at pages 16 and 17, to provide the motivation to modify Wilk. Such reliance on Appellant's disclosure and use of hindsight, however, is completely improper. The Examiner has ignored the guidance set forth in M.P.E.P. § 2142, which explains that “[k]nowledge of applicant's disclosure must be put aside in reaching this [obviousness] determination” and “impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.” Although M.P.E.P. § 2142 allows the applicant's disclosure to be “kept in mind in order to determine the ‘differences,’ conduct the search and evaluate the ‘subject matter as a whole’ of the invention,” it clearly warns against relying on that disclosure as a teaching of the missing subject matter of a reference or to provide the motivation to modify the reference to supply the missing subject matter. In this case, the Examiner went beyond looking to Appellant's own disclosure in order to determine differences, conduct the search, and evaluate the subject matter of the invention. Rather, and contrary to the rules against relying on hindsight, the Examiner relies on Appellant's disclosure to supply the motivation needed to modify Wilk. As such, the Examiner has not established a *prima facie* case of obviousness and the final rejection based on Wilk should be withdrawn.

3. Neither the Requirements For Taking Official Notice Nor For Relying on Personal Knowledge Have Been Met

To the extent the Examiner may be taking Official Notice to support the acknowledged missing disclosure or to provide motivation to modify Wilk, the Examiner

has not met the requirements for taking such Official Notice as set forth in M.P.E.P. § 2144.03. M.P.E.P. § 2144.03 cautions that reliance on Official Notice “should be rare when an application is under final rejection” and further directs that Official Notice “should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known.” The use of a preexisting natural septal opening in the manner recited in Appellant’s claims is not of such “instant and unquestionable demonstration as being well-known.” Id.

Additionally, in the Request for Reconsideration filed November 4, 2004, Appellant specifically traversed taking such Official Notice to the extent the Examiner was relying on Official Notice and requested that the Examiner supply concrete evidence to support any such reliance on Official Notice, as required by the M.P.E.P. § 2144.04. The Examiner did not supply such concrete evidence. Thus, for at least the above reasons, Appellant submits that any reliance on Official Notice for the alleged missing disclosure of Wilk and/or motivation to modify Wilk as set forth in the final Office Action and Advisory Action is improper. To the extent the final rejections are based on such Official Notice, they should be withdrawn.

Further, to the extent the Examiner may be relying on her own personal knowledge regarding the alleged knowledge of skilled artisans and surgeons, 37 C.F.R. §1.104(d)(2) requires the Examiner to supply an affidavit in the present circumstances.

When a rejection in an application is based on facts within the personal knowledge of an employee of the Office, the data shall be as specific as possible, and the reference must be supported, when called for by the applicant, by the affidavit of such employee and such affidavit shall be subject

to contradiction or explanation by the affidavits of the applicant and other persons.

37 C.F.R. §1.104(d)(2).

The Examiner has not supplied an affidavit of personal knowledge, despite Appellant having requested such affidavit at page 5 of the Request for Reconsideration filed November 4, 2004. Thus, it appears the Examiner is either not relying on personal knowledge, thereby leaving the rejection unsupported by evidence, or has not satisfied the requirements to properly establish and rely on such personal knowledge. In either case, a *prima facie* case of obviousness has not been established and the final Office Action should be withdrawn.

4. The Examiner Has Not Established Inherency

As noted above, the Examiner states at page 2 of the Advisory Action dated November 30, 2004, that “[f]or a surgeon, during surgery, it would be obvious, if not inherent to use a preexisting opening if one exists.” The Examiner further states that “the limitation not explicitly recited in Wilk would be obvious, if not inherent to one of ordinary skill in the art.”

The Examiner thus appears to be relying on some alleged inherent disclosure of use of a preexisting natural septal opening. To establish inherency, however, the Examiner must show that “the missing descriptive matter is *necessarily* present” in the reference. See M.P.E.P. §2112 quoting *In re Robertson*, 49 U.S.P.Q.2d 1949 (Fed. Cir. 1999). “The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.” M.P.E.P. § 2112 (emphasis in original.)

In the present case, the Examiner has not established that Wilk's disclosure of a forming a passageway in the heart wall and placing a stent in that passageway is necessarily a teaching of using any preexisting natural septal opening to either form a blood flow path, as required by claim 1, or to be included as part of an interstitial passageway in which a conduit is placed, as required by claims 2, 3, and 24.

Indeed, Appellant submits that it is possible to form a passageway in the heart wall and place a conduit in such a passageway, as disclosed by Wilk, without using a preexisting natural septal opening. Contrary to the Examiner's apparent conclusion regarding what would be inherent to skilled artisans and surgeons, use of such an opening is not a necessity, and is therefore not inherent. Indeed, it may be difficult for a surgeon to locate such a preexisting natural septal opening, depending on the procedure being performed for making a passageway in the heart wall. For example, a surgeon may not be able to locate, and thus use, a preexisting natural septal opening if visualization or other mapping techniques are not performed, or perhaps a preexisting natural septal opening is not located where it is desired to form a blood flow path or place a conduit. In addition, there may be reasons it would not be desirable to use a preexisting natural septal opening, such as, for example, if there were concern that damage may occur to the preexisting natural septal opening.

For at least these reasons, therefore, the Examiner has failed to establish any inherent teachings regarding the use of a preexisting natural septal opening.

**C. THE SECTION 103 REJECTION OF CLAIMS 1-3, 7, 8, AND 22-25 BASED ON
WILK SHOULD BE WITHDRAWN**

**1. The Section 103 Rejection of Independent Claim 1, and Dependent Claims 7
and 8, Should Be Withdrawn**

As discussed above in Section A, Wilk does not disclose use of a preexisting natural septal opening at all and also does not disclose "forming a blood flow path . . . via a preexisting natural septal opening," as recited in independent claim 1. Indeed, the Examiner acknowledges in the Office Action dated August 10, 2004 and in the Advisory Action dated November 30, 2004 that Wilk does not explicitly recite a preexisting natural opening.

Further, for the various reasons explained above in Section B, the final Office Action does not establish a *prima facie* case of obviousness to modify Wilk by using a preexisting natural septal opening to form a blood flow path in the manner suggested in the final Office Action. That is, the Examiner has offered no teaching of the acknowledged missing disclosure of Wilk--i.e., forming a blood flow path via a preexisting natural septal opening--nor any motivation to modify the teachings of Wilk in the manner suggested in the Office Action.

Instead, the Examiner relies on conclusory assertions regarding the "knowledge" of skilled artisans and surgeons. Such conclusory assertions, however, are completely insufficient to support a *prima facie* case of obviousness. Moreover, as explained in detail above in Section B, to the extent the Examiner is relying on principles of inherency, such alleged inherent disclosure of forming a blood flow path via a preexisting natural septal opening has not been established. In addition, as also explained above in Section B, the Examiner's final rejection of claim 1 based on Wilk appears to improperly rely on hindsight and the teachings of Appellant's own disclosure.

For at least these reasons, claim 1 is patentably distinguishable from Wilk and the Section 103 rejection of claim 1 based on Wilk should be withdrawn. Claims 7 and 8 depend from claim 1 and thus also are patentably distinguishable from Wilk for at least the same reasons claim 1 is.

2. The Section 103 Rejection of Claim 2 Should Be Withdrawn

As discussed above in Section A, Wilk does not disclose use of a preexisting natural septal opening at all and also does not disclose forming a blood flow path via a preexisting natural septal opening “wherein forming a blood flow path . . . includes placing a conduit in a heart wall,” as recited in claim 2. Indeed, the Examiner acknowledges in the Office Action dated August 10, 2004 and in the Advisory Action dated November 30, 2004 that Wilk does not explicitly recite a preexisting natural opening.

Further, for the various reasons explained above in Section B, the final Office Action does not establish a *prima facie* case of obviousness to modify Wilk by using a preexisting natural septal opening to form a blood flow path wherein forming the blood flow path includes placing a conduit in a heart wall in the manner suggested in the final Office Action. That is, the Examiner has offered no teaching of the acknowledged missing disclosure of Wilk--*i.e.*, forming a blood flow path via a preexisting natural septal opening wherein forming the blood flow path includes placing a conduit in the heart wall--nor any motivation to modify the teachings of Wilk in the manner suggested in the Office Action.

Instead, the Examiner relies on conclusory assertions regarding the “knowledge” of skilled artisans and surgeons. Such conclusory assertions, however, are completely insufficient to support a *prima facie* case of obviousness. Moreover, as explained in

detail above in Section B, to the extent the Examiner is relying on principles of inherency, such alleged inherent disclosure of forming a blood flow path via a preexisting natural septal opening wherein forming the blood flow path includes placing a conduit in the heart wall has not been established. In addition, as also explained above in Section B, the Examiner's final rejection of claim 1 based on Wilk appears to improperly rely on hindsight and the teachings of Appellant's own disclosure.

For at least these reasons, in addition to those discussed with respect to claim 1, claim 2 is patentably distinguishable from Wilk and the Section 103 rejection of claim 2 based on Wilk should be withdrawn.

3. The Section 103 Rejection of Claim 3 Should Be Withdrawn

As discussed above in Section A, Wilk does not disclose use of a preexisting natural septal opening at all, let alone "placing a conduit in the preexisting natural septal opening" as recited in claim 3. Indeed, the Examiner acknowledges in the Office Action dated August 10, 2004 and in the Advisory Action dated November 30, 2004 that Wilk does not explicitly recite a preexisting natural opening.

Further, for the various reasons explained above in Section B, the final Office Action does not establish a *prima facie* case of obviousness to modify Wilk by placing a conduit in a preexisting natural septal opening in the manner suggested in the final Office Action. That is, the Examiner has offered no teaching of the acknowledged missing disclosure of Wilk--*i.e.*, placing a conduit in the preexisting natural septal opening--nor any motivation to modify the teachings of Wilk in the manner suggested in the Office Action.

Instead, the Examiner relies on conclusory assertions regarding the "knowledge" of skilled artisans and surgeons. Such conclusory assertions, however, are completely insufficient to support a *prima facie* case of obviousness. Moreover, as explained in detail above in Section B, to the extent the Examiner is relying on principles of inherency, such alleged inherent disclosure of placing a conduit in the preexisting natural septal opening has not been established. In addition, as also explained above in Section B, the Examiner's final rejection of claim 1 based on Wilk appears to improperly rely on hindsight and the teachings of Appellant's own disclosure.

For at least these reasons, in addition to those discussed with respect to claims 1 and 2, claim 3 is patentably distinguishable from Wilk and the Section 103 rejection of claim 3 based on Wilk should be withdrawn.

4. The Section 103 Rejection of Independent Claim 24, and Dependent Claims 22, 23, and 25, Should Be Withdrawn

As discussed above in Section A, Wilk does not disclose use of a preexisting natural septal opening at all, let alone "placing a conduit in the interstitial passageway . . . wherein the interstitial passageway includes a preexisting natural septal opening," as recited in claim 24. Indeed, the Examiner acknowledges in the Office Action dated August 10, 2004 and in the Advisory Action dated November 30, 2004 that Wilk does not explicitly recite a preexisting natural opening.

Further, for the various reasons explained above in Section B, the final Office Action does not establish a *prima facie* case of obviousness to modify Wilk by placing a conduit in an interstitial passageway that includes a preexisting natural septal opening in the manner suggested in the final Office Action. That is, the Examiner has offered no teaching of the acknowledged missing disclosure of Wilk--i.e., placing a conduit in an

interstitial passageway that includes a preexisting natural septal opening--nor any motivation to modify the teachings of Wilk in the manner suggested in the Office Action.

Instead, the Examiner relies on conclusory assertions regarding the "knowledge" of skilled artisans and surgeons. Such conclusory assertions, however, are completely insufficient to support a *prima facie* case of obviousness. Moreover, as explained in detail above in Section B, to the extent the Examiner is relying on principles of inherency, such alleged inherent disclosure of placing a conduit in an interstitial passageway that includes a preexisting natural septal opening has not been established. In addition, as also explained above in Section B, the Examiner's final rejection of claim 1 based on Wilk appears to improperly rely on hindsight and the teachings of Appellant's own disclosure.

For at least these reasons, independent claim 24 is patentably distinguishable from Wilk and the Section 103 rejection of claim 24 based on Wilk should be withdrawn.

For at least the reasons above, the Examiner has failed to establish a *prima facie* case of obviousness of claims 1-3, 7, 8, and 22-25 and thus Applicant respectfully requests withdrawal of the Section 103(a) rejection based on Wilk.

Conclusion

For the reasons explained above, the final Office Action has not established a *prima facie* case of obviousness and the Section 103 rejection of claims 1-3, 7, 8, and 22-25 based on Wilk should be withdrawn. Because claims 1 and 24 are allowable, Appellant submits that withdrawn claims 4-6, 9, 10, 14-20, and 26-29, which depend from one of claims 1 and 24, should be rejoined and also allowed, as set forth in M.P.E.P. § 821.04.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: March 8, 2005

By: Susanne T. Jones
Susanne T. Jones
Reg. No. 44,472



Application No.: 09/769,746
Attorney Docket No.: 07883.0106

Appealed Claims Appendix to Appeal Brief Under Rule 41.37(c)(1)(viii)

1. A method for supplementing a flow of blood to a portion of the cardiovascular system of a patient, the method comprising:

inserting a catheter device into the vasculature of the patient and advancing the catheter device to a first location within a first coronary vessel within the cardiovascular system; and

forming a blood flow path from a heart chamber directly to the first coronary vessel via a preexisting natural septal opening extending into the heart wall between the heart chamber and the first coronary vessel.

2. The method according to claim 1, wherein forming a blood flow path from the heart chamber directly to the first coronary vessel includes placing a conduit in a heart wall between the heart chamber and the first coronary vessel.

3. The method according to claim 2, wherein placing a conduit in a heart wall between the heart chamber and the first coronary vessel includes placing a conduit in the preexisting natural septal opening.

7. The method according to claim 1, wherein the first coronary vessel is a coronary artery.

8. The method according to claim 7, wherein the coronary artery is a left anterior descending coronary artery.

22. The method according to claim 24 further comprising distending the obstruction within the coronary vessel.

23. The method according to claim 22, wherein distending the obstruction within the coronary vessel includes inflating a balloon at the obstruction within the coronary vessel.

24. A method for supplementing a flow of blood to a portion of the cardiovascular system of a patient, the method comprising:

(a) inserting a catheter device into the vasculature of the patient and advancing the catheter device to a first location within a coronary vessel within the cardiovascular system, the first location being proximate to an obstruction within the coronary vessel;

(b) advancing the catheter device through the obstruction to a second position distal to the obstruction;

(c) guiding the catheter device through an interstitial passageway extending into a heart wall between a heart chamber and the coronary vessel; and

(d) placing a conduit in the interstitial passageway extending into the heart wall between the heart chamber and the coronary vessel,

wherein the interstitial passageway includes a preexisting natural septal opening extending into the heart wall between the heart chamber and the coronary vessel.

25. The method according to claim 24, wherein the coronary vessel is a coronary artery.

Application No.: 09/769,746
Attorney Docket No.: 7883.0106

Evidence Appendix to Appeal Brief Under Rule 41.37(c)(1)(ix)

None.

Application No.: 09/769,746
Attorney Docket No.: 7883.0106

Related Proceedings Appendix to Appeal Brief Under Rule 41.37(c)(1)(x)

None.